

### **REMARKS**

Reconsideration and withdrawal of the rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 83-85 are added, claims 63-64, 66 and 68 are amended. Claims 53-55, 58-60, 63-64, 66-68, 70, 72-74, 78-79, and 81-85 are pending.

The Examiner rejected claims 53-55, 63-64, 66-68, 70, 72-74, 78-79, and 81-82 under 35 U.S.C. § 101 for lack of a specific or well-established utility. Applicant respectfully traverses this rejection.

An applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. § 101 in most cases. See M.P.E.P. § 2107.02, III.A, pages 2100-30 (citing *In re Jolles*, 628 F.2d 1322, 206 U.S.P.Q. 885 (C.C.P.A. 1980); *In re Irons*, 340 F.2d 974, 144 U.S.P.Q. 351 (C.C.P.A. 1965); *In re Langer*, 503 F.2d 1380, 183 U.S.P.Q. 288 (C.C.P.A. 1974); and *In re Sichert*, 566 F.2d 1154, 1159, 196 U.S.P.Q. 209, 212-13 (C.C.P.A. 1977), to support the concept that an asserted utility creates a presumption of utility). Thus, when an applicant has specifically asserted that an invention has a particular utility, the Examiner must presume that the assertion is true. See M.P.E.P. § 2107.02, III.B, page 2100-30 (citing *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974); *In re Malachowski*, 530 F.2d 1402, 1404, 189 U.S.P.Q. 432, 435 (C.C.P.A. 1976); and *In re Brana*, 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995)).

An assertion of utility is credible *unless* (A) the logic underlying the assertion is seriously flawed or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. See M.P.E.P. § 2107.02, III.B, page 2100-31. The Examiner must establish that it is more likely than not that one of ordinary skill in the art would doubt the truth of the statement of utility. Examples of when an asserted utility is not credible include: (A) where a person of ordinary skill would consider the assertion to be “incredible in view of contemporary knowledge” and where nothing offered by the applicant would counter what contemporary knowledge might otherwise suggest; (B) where the applicant failed to disclose any utility; (C) where the applicant asserted a utility that could only be true if it violated a scientific principle, such as the second law of thermodynamics or a law of nature; or (D) where the applicant asserted a utility that was wholly inconsistent with contemporary knowledge in the art

(citing *In re Gazave*, 379 F.2d 973, 978, 154 U.S.P.Q. 92, 96 (C.C.P.A. 1967)) (emphasis in original).

In the present case, Applicant has asserted that the detection of variant PBR, e.g., those with a substitution at position 147 or position 162, in cells may be useful, for example, to detect the aggressive nature of cancer, and that variant PBR nucleic acid may be useful to alter PBR expression in cells that express the corresponding variant PBR. Applicant's assertion of utility is presumed to be credible unless the Examiner establishes a *prima facie* case of lack of utility as discussed above. See M.P.E.P. § 2107.02, IV, page 2100-31 (citing *In re Gaubert*, 524 F.2d 1222, 1224, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) as stating "[a]ccordingly, the PTO must do more than merely question operability - it must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability.").

As to the logic underlying Applicant's assertion, prior to Applicant's filing date, there were reports of numerous mutant genes that were associated with cancer, e.g., the p60src gene, the retinoblastoma gene, and the ras gene (see Hanafusa et al., Princess Takamutsu Symp., 17:233 (1986), Weinberg, Cancer Surv., 12:43 (1992)), London et al., Princess Takamutsu Symp., 25:51 (1995), and Abrams et al., Semin. Oncol., 23:118 (1996)) (all of record).

Moreover, the facts, e.g., the specification, the Rule 132 Declaration of Dr. Papadopoulos filed on October 12, 2006, and the abstracts for Morgan et al., Br. J. Dermatol., 151:846 (2004), Maaser et al., Clin. Cancer Res., 8:3205 (2002), and Han et al., J. Receptors and Signal Transd., 23:225 (2003) (all of record), support Applicant's assertion .

The Examiner alleges that the Rule 132 Declaration of Dr. Papadopoulos "shows that only one mutation, at position 147, exists in colon and breast cancer biopsies" (page 3 of the Office Action). In this regard, the Examiner is requested to consider the enclosed abstract by Kurumaji et al. (J. Neural. Transm., 107:491 (2000)) which reports that human PBR alleles having Ala147Thr or His162Arg were identified in patient samples, and that there was an increased frequency of the His162Arg allele in schizophrenics.

Therefore, the Examiner has not established a *prima facie* case showing that Applicant's invention lacks utility. Accordingly, Applicant respectfully requests withdrawal of the 35 U.S.C. § 101 rejection.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

VASSILIOS PAPADOPOULOS ET AL.

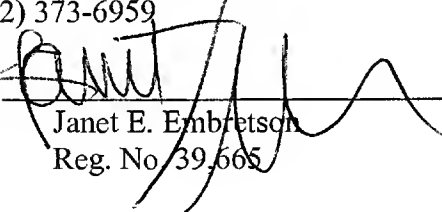
By their Representatives,

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Date

March 2, 2007

By

  
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**CERTIFICATE UNDER 37 CFR 1.8:** The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 2 day of March 2007.

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Signature

